Supreme Court
FILED

No. 03-1610 MAY 28 2004

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

JULIAN M. WHITAKER, M.D.; DURK PEARSON; SANDY SHAW; AND THE AMERICAN ASSOCIATION FOR HEALTH FREEDOM,
Petitioners,

v.

TOMMY G. THOMPSON, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; LESTER M. CRAWFORD, ACTING COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION; FOOD AND DRUG ADMINISTRATION; AND THE UNITED STATES OF AMERICA,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Should the exclusion from First Amendment protection for speech related to an unlawful activity in the first prong of *Central Hudson Gas & Electric Corp. v. Public Service Commission* apply to proposed dietary supplement labeling that has not appeared in the market and is solely the subject of a petition for health claim approval to the Food and Drug Administration (FDA)?

2. Should the avoidance doctrine be invoked only upon proof of "a comparatively high likelihood of unconstitutionality" or "at least some exceptional intricacy of constitutional doctrine?"

3. Should FDA's statutory interpretation be accorded deference despite plain statutory language to the contrary; despite Congressional pre-enactment knowledge of, but failure to adopt, FDA's favored meaning; and despite legislative intent contrary to the agency's interpretation?

PARTIES TO THE PROCEEDING

All parties to the proceeding are listed in the case caption.

RULE 29.6 STATEMENT

Petitioner American Association for Health Freedom is a non-profit corporation under Virginia law. There is no parent or publicly held company owning 10% or more of the corporation's stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Julian M. Whitaker, M.D., et al. respectfully petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The March 9, 2004 order of the District of Columbia Circuit denying the petition for rehearing *en banc* (53a of the Appendix (hereinafter "Pet. App.")) is unpublished. The

January 9, 2004 panel opinion of the District of Columbia Circuit affirming the opinion of the United States District Court for the District of Columbia (Pet. App. at 1a) is reported at 353 F.3d 947 (D.C. Cir. 2004). The January 3, 2003 opinion of the District Court dismissing Julian M. Whitaker, et al.'s complaint (Pet. App. at 11a) is reported at 239 F.Supp. 2d 43 (D.D.C. 2003).

JURISDICTION

The District of Columbia Circuit entered its *en banc* order on March 9, 2004. Pet. App. at 53a. This petition for certiorari is timely in that Petitioner has filed it within 90 days of March 9, 2004. The Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS

The First Amendment to the United States Constitution provides in pertinent part: "Congress shall make no law * * * abridging the freedom of speech * * *."

The Appendix (at 54a) reproduces the following provisions of the Federal Food, Drug, and Cosmetics Act: 21 U.S.C. §§ 321(g), 321(m), 321(ff), 343(r)(1)(B), 343(r)(5)(D), 355(a), 355(b)(1), 355(c)(2), and 355(c)(3)(D).

The Appendix (at 70a) reproduces the following regulations of the Food and Drug Administration pertaining to health claim petitions: 21 C.F.R. §§ 101.14, 101.70, and 101.75.

STATEMENT OF THE CASE

1. The Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (NLEA), amending the federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 *et seq.*), creates an exception to drug classification (21 U.S.C. § 321(g)(1)(D) (2000)) for dietary supple-

ments that have "health claims" on their labels. A health claim is a statement that "characterizes the relationship of any nutrient . . . to a disease or a health-related condition." 21 U.S.C. § 343(r)(1)(B) (2000). On its face the statutory health claim language is broad, embracing all nutrient-disease relationships. No health claim may be placed on the label or in the labeling of a dietary supplement without prior FDA approval or allowance, regardless of the health claim's truthfulness. *See* 21 U.S.C. § 343(r)(5)(D) (2000), 21 C.F.R. § 101.70 (2004) (prescribing pre-approval through rule-making); *see also Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g en banc denied*, 172 F.3d 72. In the FDCA section 201(m) (21 U.S.C. § 321(m) (2000)), "labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

On May 25, 1999, the Petitioners filed a petition for a health claim with FDA pursuant to 21 U.S.C. § 343(r)(5)(D) and 21 C.F.R. § 101.70 before any use of the claim in the market. Compl. ¶¶ 1-2.[1] The Petitioners sought FDA premarket authorization for a health claim associating an extract of the fruit of the dwarf American palm tree, saw palmetto, with reduction in certain symptoms of mild benign prostatic hyperplasia (BPH). BPH is a benign condition of the prostate that causes it to become enlarged, to reduce urine flow, and to create voiding urgency. Compl. ¶ 21. BPH afflicts 40 to 50% of men over the age of 50. Br. for Appellants at 2, n.2. The Petitioners' health claim reads: "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)."

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[1] "Compl." refers to Whitaker et al.'s Complaint filed in the U.S. District Court for the District of Columbia.

Saw palmetto has been sold across the United States as a dietary supplement and has been labeled as supporting "prostate health" for decades, all without FDA objection. Br. for Appellants at 4. From the 1700's to the present, saw palmetto extract has been used as a food and as a nutritional tonic by certain Native Americans. Br. for Appellants at 4. Saw palmetto extract is unpatentable. *See* Br. for Appellants at 17, citing SMJ[2] at 38, n. 26 (Ex. 12).

In this case, FDA interpreted 21 U.S.C. § 343(r)(1)(B) to constrict the definition of a health claim by excluding any statement concerning the "effect [of a nutrient] on an existing disease." Pet. App. at 34a, 36a. *Whitaker v. Thompson*, 239 F.Supp.2d 43, 47 (D.D.C. 2003). FDA denied the Petitioners' health claim without review because FDA declared it to be such a statement. FDA stated that it would allow the claim only if the nutrient were pre-approved as a new drug. *See*, Pet. App. at 45a; *see also*, Br. for Fed. Appellees at 55. Prior to its action on Petitioners' health claim, FDA had not interpreted 21 U.S.C. § 343(r)(1)(B) to prohibit claims of a nutrient's effect on existing disease. Rather, FDA described the matter as "novel" in its decision letter on the Petitioners' health claim. *Id.* at 90a.

FDA denied Petitioners' health claim without evaluating the science on safety and efficacy supporting it. FDA held the nutrient-disease relationship in the claim could only be communicated to the public if saw palmetto, an unpatentable nutrient, was first approved by FDA as a drug. Br. for Fed. Appellees at 18-20. FDA did not argue that the claim is untruthful or misleading. *See* Br. for Fed. Appellees at 18-21. The FDCA's drug provisions contemplate patentability as a condition precedent and include provisions to extend patent protection. 21 U.S.C. § 355 (b)(1), (c)(2) and (c)(3)(D) (2000

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[2] "SMJ" refers to Whitaker et al.'s Motion for Summary Judgment filed in the U.S. District Court for the District of Columbia.

& Supp. I. 2002). Saw palmetto is commonly sold nationwide in a competitive free market as a dietary supplement. FDA has stated that foods, a category that includes dietary ingredients like saw palmetto extract, are likely incapable of meeting the substantive requirements for drug approval. 52 Fed. Reg. 28843, 28845 (Aug. 4, 1987) ("[F]ood products are not likely . . . to have disease prevention claims substantiated in a manner necessary for approval of a new drug application"). Monopoly returns achievable for patentable drugs are unachievable for saw palmetto extract, making recoupment of the extraordinary costs of drug approval impossible for those who sell saw palmetto extract. *See* Br. for Appellants at 6, citing MSJ at 14, Ex. 5, 7-11. The estimated cost of new drug approval for saw palmetto extract would be at least $58 million, based in large measure on the kinds of original research that would have to be performed to support a rule compliant new drug application. *Id.* None of the petitioners desires to market saw palmetto as a drug. *Id.* None has the financial wherewithal to prepare, file and prosecute a rule compliant new drug application for saw palmetto extract. *Id.*

2. In their complaint the Petitioners challenged FDA's suppression of the saw palmetto health claim as (1) a violation of the federal Food Drug and Cosmetic Act (FDCA) health claims provision by erroneously excluding from the definition of nutrient-disease relationship claims in 21 U.S.C. § 343(r)(1)(B) claims that concern effects of nutrients on existing disease; (2) a violation of the First Amendment to the United States Constitution by suppressing truthful and non-misleading scientific and commercial speech needed for the exercise of informed choice in the market; (3) a violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), by arbitrarily and capriciously ruling against review of the saw palmetto health claim when FDA had previously approved a low-fat diet, cholesterol lowering health claim (21 C.F.R. § 101.75 (2002)) that did concern the effect of nutrients (fats)

on existing disease (hypercholesterolemia); and (4) a violation of the Supremacy Clause of the United States Constitution by choosing to implement a speech suppressive agency rule over the speech protective command of the First Amendment. *See* Pet. App. at 12a. The United States District Court for the District of Columbia granted the government's motion to dismiss the complaint for failure to state a claim. *Id.* at 31a.

The District Court held Congress' intent concerning the scope of health claims in 21 U.S.C. § 343(r)(1)(B) ambiguous warranting deference to FDA's interpretation under *Chevron* step two. Pet. App. at 24a. The Court concluded that FDA's decision to limit health claims to disease prevention was reasonable in light of FDA's prior history of regulating articles as drugs based on their intended use. *Id.* at 24a, 27a. The Court reasoned that there was no First Amendment impediment to suppression of the dietary supplement health claim, concluding under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), that FDA's decision to classify the saw palmetto claim as a drug claim made it unlawful for use and, as such, commercial speech about an unlawful activity proscribable under *Central Hudson's* first prong.

The panel of the United States Court of Appeals for the D.C. Circuit affirmed unanimously. Pet. App. at 1a. The panel found the definition of a "drug" in 21 U.S.C. § 321(g)(1)(B) ("articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease") to overlap with the definition of a dietary supplement "health claim" in 21 U.S.C. § 343(r)(1)(B) (claims that "characterize[] the relationship of a nutrient . . . to a disease or health-related condition"). Pet. App. at 3a. It found no guiding statutory principles to determine when statements would be allowable as dietary supplement health claims. *Id.* at 3a, 4a.

The panel focused its statutory construction analysis on an exception from drug status for dietary supplements bearing FDA approved health claims and for dietary supplements bearing claims of a nutrient's effect on a body structure or function, 21 U.S.C. § 321(g)(1)(D).[3] The panel identified three possible interpretations for the statutory language in 21 U.S.C. § 321(g)(1)(D) and rejected each one: (1) that a health claim could not alone be evidence of an intent to sell a drug but could constitute that evidence if accompanied by other evidence of intent to sell a drug; (2) that all claims that a nutrient diagnoses, cures, mitigates, treats, or prevents a disease are "health claims" and a food or dietary supplement bearing a health claim is exempt from drug regulation;[4] and (3) that some health claims that would otherwise be drug claims are exempted, the exempt class determinable by FDA. Pet. App. at 4a-5a.

The panel evaluated FDA's argument that section 343(r)(1)(B) excludes statements claiming an effect of a nutrient on an existing disease under the framework established in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron* step one, the panel thought the intent of Congress ambiguous on the

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[3] The panel erroneously cited the last sentence of 21 U.S.C. § 321(g)(1)(D). Pet. App. at 3a. That sentence refers to section 406(r)(6) (21 U.S.C. § 343 (r)(6) (2000)), an exemption from drug classification not for health claims but for claims about a nutrient's effect on a body structure or function. The relevant language appears in the second to the last sentence of 21 U.S.C. § 321(g)(1)(D). The second to the last sentence concerns health claims and provides that a dietary supplement is not a drug solely because the label or labeling contains a FDA-approved health claim.

[4] Only those claims about a nutrient's effects on a disease that have been reviewed prior to publication and approved (or allowed) by FDA in response to a petition can qualify as health claims. 21 U.S.C. § 343(r)(3); *see also Pearson*, 164 F.3d at 659; *Whitaker v. Thompson*, 248 F.Supp. 2d 1, 27 (D.D.C. 2002).

"drug"/"health claim" distinction and, so, turned to step two to discern whether FDA's exclusion of claims concerning a nutrient's effect on existing disease was reasonable. The panel found examples of health claims in the legislative history worded as "prevention" claims. The panel also found that Congress ordered FDA to evaluate ten possible health claims that the panel stated concerned reduction in chronic disease risk. Pet. App. at 6a. The panel observed that FDA had a long history of regulating as unapproved drugs those foods and dietary supplements that were accompanied by treatment claims. *Id.* at 7a. It also identified certain FDA policy considerations said to support drug regulation: that the health of diseased populations was particularly vulnerable and, so, warranted more regulation; that claims of a nutrient's effect on existing disease might lull people into a false sense of security, leading them to delay visits to the doctor for disease diagnosis; and that if products could escape drug regulation the drug approval process and incentives for drug research would be diminished. *Id.* The panel found none of FDA's arguments for its constriction of the health claim definition particularly persuasive, writing:

> None of these is a knock-down argument, and we doubt that any of them would be sufficient to overcome a strong textual or structural inference in favor of a different interpretation. Certainly there is nothing in the two statutory definitions [for drugs and for dietary supplement health claims, respectively] that would obviously equate claims of "treatment" with drug claims and of "prevention" with health claims. But given our finding that the statute is ambiguous . . ., the legislative history and statutory context invoked by FDA are enough to render its interpretation reasonable.

Id. at 7a-8a.

The panel rejected the Petitioners' Administrative Procedure Act and avoidance doctrine arguments along with their First Amendment claim. The panel found FDA's explanation

for authorization of its low-fat, cholesterol-lowering claim as a health claim "plausible," and not evidence of a prior FDA authorization of a claim concerning the effect of nutrients on existing disease. *Id.* at 8a.

The panel did not invoke the avoidance doctrine to trump *Chevron* deference, holding the doctrine not appropriately invoked without "a comparatively high likelihood of unconstitutionality, or at least some exceptional intricacy of constitutional doctrine." *Id.* at 8a-9a. The panel did not find Petitioners' First Amendment objection "so powerful" as to cause the panel "to abandon or qualify *Chevron* deference." *Id.*

Responding to Petitioners' First Amendment argument, the panel agreed that the district court had engaged in "completely circular" reasoning when it held Petitioners' health claim "speech related to unlawful activity" under *Central Hudson*, 447 U.S. 557, solely due to FDA's classification of the speech as unlawful. Pet. App. at 10a. The panel affirmed the district court's holding, however, despite the circularity. *Id.* Citing to a criminal case that relied on racist statements as aggravating circumstances for sentencing, *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993), the panel held the proposed health claim to be evidence of Petitioners' intent to sell their saw palmetto extract dietary supplements as drugs because the petitioned claims, if used in the market without FDA approval, would be evidence of the unlawful sale of an unapproved new drug. The panel ruled that, under *Mitchell*, a health claim presented in a petition for FDA premarket approval was evidence of criminal intent and, on that basis, could be banned outright under the first prong of *Central Hudson*. *Id.* The panel did not reach the remaining *Central Hudson* prongs. It affirmed the district court's dismissal of Petitioners' complaint. *Id.*

The Circuit Court issued an order per curiam on March 9, 2004, denying rehearing en banc. Pet. App. at 53a.

REASONS FOR GRANTING THE WRIT

The Petition for a Writ of Certiorari should be granted for four reasons. First, the panel's decision that a speech ban is unreviewable under the First Amendment because it renders use of the speech unlawful activity cannot be reconciled with this Court's controlling commercial speech precedent and the commercial speech decisions of the other circuits. Indeed, the decision so vastly expands the scope of *Central Hudson's* first prong exclusion from First Amendment protection as to envelop the rule. Second, the panel's decision to defer to FDA's interpretation of 21 U.S.C. § 343(r)(1)(B) (excluding from the health claim definition statements that concern the effects of nutrients on existing disease) in the presence of a serious First Amendment question directly conflicts with this Court's avoidance doctrine precedent and with the avoidance doctrine decisions of the other circuits. Third, the panel's decision violates this Court's canons of statutory construction by condoning an interpretation of the health claim definition in 21 U.S.C. § 343(r)(1)(B) that flatly contradicts (1) the plain meaning of the statutory language; (2) the fact that Congress knew of FDA's desired definition but did not adopt it; and (3) language in the House Report on the bill referring to disease treatment claims in reference to health claims. Finally, the decision has profound precedential import. It greatly expands the scope of the first prong of *Central Hudson*, negating the utility of the four-part test by excepting from First Amendment protection all speech censored on pain of criminal sanction (here going so far as to suppress commercial speech *proposed* to the government in a *petition for redress*, but not used in the market). In addition, the panel's decision effectively locks out of the food market at the point of sale[5] all manner of truthful information about the effects of

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[5] The labeling of a food or dietary supplement has been found the most effective means of communicating health information to a consumer. *See Pearson*, 164 F.3d at 658 n.7 (citing John E. Calfee & Janis K. Pap-

unpatentable foods and dietary ingredients on existing disease. The suppression causes Americans with diseases who, if adequately informed, could modify their diets in ways that would lessen the length or severity of those diseases to proceed unaware and to suffer needlessly.

I. THE DECISION BELOW CONFLICTS WITH *CENTRAL HUDSON GAS & ELECTRIC CORP.* AND ITS PROGENY BY HOLDING TRUTHFUL COMMERCIAL SPEECH "SPEECH RELATED TO UNLAWFUL ACTIVITY" UNPROTECTED BY THE FIRST AMENDMENT DESPITE THE ABSENCE OF ANY ILLEGAL ACT

Since the adoption of the test for evaluating restrictions on commercial speech in *Central Hudson Gas & Electric Corp.*, 447 U.S. at 562-63 (1980), this Court has assessed speech bans and restrictions that carry with them civil and criminal penalties under all four *Central Hudson* prongs. This Court has never held government speech bans and restrictions "speech related to illegal activity." *See, e.g., Rubin v. Coors*, 514 U.S. 476, 482 (1995). The fact that the government rule in question defines speech as illegal is precisely the First Amendment question for which judicial review is required. Were the panel's interpretation of the meaning of *Central Hudson*'s first prong the law of the land, the exception from First Amendment protection in the first prong would envelop the rule, and *Central Hudson* itself could not have been decided. There the Court evaluated a ban which made promotional advertising by electric utilities illegal. *Id.* at 558-59.

It is an unremarkable fact that every challenge to a commercial speech restriction heard by this Court involves a challenge to a law that makes it illegal to utter the speech in

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palardo, *How Should Health Claims for Foods Be Regulated?* 26-27 (Bureau of Economics, Federal Trade Commission 1989)).

question, yet in no instance did this Court interpret that illegality as proof that the speech was related to an illegal activity. The panel's decision offers nothing to distinguish the case before it from this Court's entire post-*Central Hudson* commercial speech jurisprudence. To be sure, this Court has rejected extreme deference to the judgment of law-making bodies on whether commercial speech is deserving of First Amendment protection, holding such deference inconsistent with the Court's constitutional review function. *See 44 Liquormart, v. Rhode Island*, 517 U.S. 484, 509-10 (1996) (plurality opinion).

No petition asking the government to lift a prior restraint on the communication of truthful commercial speech has ever been denied review on the circular argument that if government deems use of the speech illegal, then the speech is not reviewable under the First Amendment.[6] The Court has not

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[6] For example, in *44 Liquormart*, 517 U.S. 484, the speech in issue (alcohol price advertising) related to a Rhode Island law that prohibited as a misdemeanor such advertising, yet the speech was not held "related to unlawful activity." In *Edenfield v. Fane*, 507 U.S. 761 (1993), the speech in issue (a direct, personal solicitation of business for a CPA practice) violated a Florida Board of Accountancy ban on such solicitations, yet the speech was not held "related to unlawful activity." In *Ibanez v. Florida Department of Business and Professional Regulation*, 512 U.S. 136 (1994), the speech in issue (prohibition of false and misleading advertising extended to an attorney/ CPA's accurate listing of credentials on law office stationery) related to the Florida Board of Accountancy's prohibition, yet the speech was not held "related to unlawful activity." In *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91 (1990), the speech in issue (letterhead listing attorney as certified with the National Board of Trial Advocacy) related to an Illinois Attorney Registration and Disciplinary Commission ban on any attorney claim of certification or specialty, yet the speech was not held "related to an unlawful activity." In *Zauderer v. Office of Disciplinary Counsel of the Sup. Ct.*, 471 U.S. 626 (1985), the speech in issue (an attorney's advertisement for legal services) related to the Ohio Professional Responsibility Code restrictions on attorney advertising, yet the speech was not held "related to an unlawful activity." In *Thompson v. Western States Medical*

abdicated its First Amendment review function because the government entity suppressing speech defines utterance of the speech unlawful activity. *E.g., 44 Liquormart*, 517 U.S. at 509. Rather, this Court places the burden of proof on government to justify actions that suppress truthful commercial speech under each prong of *Central Hudson*. *See, e.g., Edenfield*, 507 U.S. at 770 (citations omitted) ("It is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *In re R.M.J.*, 455 U.S. 191, 203-204 (1982); *see also, Peel*, 496 U.S. at 109(the potential for misleading speech does not satisfy the State's heavy burden of justifying a categorical prohibition on the dissemination of accurate factual information to the public) (citations omitted). In the absence of misleading speech, the presence of unlawful activity is an essential condition precedent to denying protection under *Central Hudson*'s first prong. *See, e.g., W. States Med. Ctr.*, 535 U.S. at 368.

In this case at no time did the Petitioners actually use their health claim in the market precisely because that would violate FDA's prior restraint on health claims. Compl. ¶¶ 1-2. Rather, without using the claim in the market, they petitioned the FDA, as prescribed by regulation, 21 C.F.R. §§ 101.14 and 101.70 (2004), seeking FDA authorization for use of the claim. They were thus dutiful in petitioning the government for a redress of their grievance and in avoiding a law violation. In short, the Petitioners have not violated the law and do not harbor an intent to commit an illegal act. By seeking FDA's pre-market approval, they complied fully with the law. The panel, however, held the language of the petitioned claim itself "evidence of an intent to commit an illegal

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Center, 535 U.S. 357 (2002), the speech in issue (advertising of drug compounding services) related to the FDCA prohibition on such advertising, yet the speech was not found "related to an unlawful activity."

act" (the sale of an unapproved new drug). On that basis, the panel invoked the exclusion from First Amendment protection contained in the first *Central Hudson* prong.

The panel decision greatly expands the scope of *Central Hudson's* first prong, creating a precedent that can be used to exclude from First Amendment evaluation virtually every regulation of commercial speech. It extends the category of unprotected speech far beyond the first prong's literal meaning, against the precedent of this Court and of the other circuits. It causes truthful commercial speech to be held to relate to unlawful activity when there is no criminal act present and when none is intended. This Court should exercise its discretionary review to correct the erroneous decision and prevent it from forming a major obstacle to application of all four *Central Hudson* prongs to evaluate government suppression of commercial speech.

II. THE DECISION BELOW DIRECTLY CONTRADICTS THIS COURT'S AVOIDANCE DOCTRINE DECISIONS BY REFUSING INVOCATION OF THAT DOCTRINE WITHOUT "A COMPARATIVELY HIGH LIKELIHOOD OF UNCONSTITUTIONALITY" OR "AT LEAST SOME EXCEPTIONAL INTRICACY OF CONSTITUTIONAL DOCTRINE"

Petitioners consistently argued that the plain meaning of 21 U.S.C. § 343(r)(1)(B) ("characterizes the relationship of any nutrient . . . to a disease or health-related condition") should govern because there is no expressed intention by Congress to the contrary, Br. for Appellants at 20-21; indeed, there is evidence Congress understood health claims to include claims of the effect of a nutrient on an existing disease. H.R. REP. NO. 101-538, at 9; Pub.L.No. 101-535, 104 Stat. 2353 (Feb. 13, 1990). The panel held the language ambiguous, however,

and accorded deference to FDA's interpretation under *Chevron* step two. Pet. App. at 5a. Assuming *arguendo* that the panel did not err by proceeding to *Chevron* step two, the Petitioners explained that step two deference would nevertheless be trumped by the avoidance doctrine in light of the serious First Amendment questions raised by FDA's ban on the dissemination of truthful nutrient-disease relationship information.

Under the avoidance doctrine, a statute is to be construed to avoid a constitutional issue unless the construction is plainly contrary to the intent of Congress. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988). No deference is due an administrative agency if the agency's construction would raise a "serious constitutional issue." *E.g., NLRB v. Catholic Bishop of Chicago*, 440 U.S. 490, 500-501 (1979).

The panel refused to apply the avoidance doctrine, holding that it may only be invoked if there exists "a comparatively high likelihood of unconstitutionality" or "exceptional intricacy of constitutional doctrine." Pet. App. at 8a-9a. Neither this Court nor any other circuit has required a comparatively high likelihood of unconstitutionality or at least some exceptional intricacy of constitutional doctrine as a condition precedent to invocation of the avoidance doctrine.[7] Rather,

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[7] *See, e.g., DeBartolo*, 485 U.S. at 575 (". . . when an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress") (citations omitted); *Catholic Bishop of Chicago*, 440 U.S. at 500-501 (invoking avoidance doctrine in presence of "serious First Amendment questions"); *Psinet, Inc. v. Chapman*, 362 F.3d 227, 236 (4th Cir. 2004); *United States v. Awadallah*, 349 F.3d 42, 55 (2d Cir. 2003); *United States v. Hernandez*, 314 F.3d 430 (9th Cir. 2002); *Mahadeo v. Reno*, 226 F.3d 3, 10 (1st Cir. 2000); (applies avoidance doctrine in a First Amendment challenge to a state statute without requiring either high likelihood of unconstitutionality or intricacy of constitutional doctrine); *George v. Nat'l*

when a First Amendment issue is squarely presented, as it is here, this Court and the other circuits have refrained from deferring to an agency's statutory interpretation, trumping *Chevron* step two in the process. *See, e.g., Catholic Bishop of Chicago*, 440 U.S. at 501. The panel's heightening of the legal standard for invocation of the doctrine is unprecedented. It has replaced the requirement of a serious constitutional issue with something akin to a summary judgment standard (comparatively high likelihood of unconstitutionality) or with a complex litigation standard (exceptional intricacy of constitutional doctrine). The panel's heightened standards are contrary to the constitutional issue requirement this Court has employed for over 200 years and that the other circuits have followed.[8] *See supra* n. 7.

This Court should exercise its discretionary review to protect the avoidance doctrine from misapplication in the D.C. Circuit. Because so many federal administrative agency rulings are appealed to the D.C. Circuit, the need for review is acute.

Ass'n of Letter Carriers, 185 F.3d 380, 387 (5th Cir. 1999), *amended by* 322 F.3d 592, 602 (9th Cir. 2003) ("Courts can and should continue to adopt statutory interpretations, when feasible, that will avoid serious constitutional issues").

[8] *See De Bartolo*, 485 U.S. at 575 citing (*Int'l Assn. of Machinists v. Street*, 367 U.S. 740, 749-50 (1961)); *Crowell v. Benson*, 285 U.S. 22, 62 (1932); *Lucas v. Alexander*, 279 U.S. 573, 577 (1929); *Panama R. Co. v. Johnson*, 264 U.S. 375, 395 (1924); *United States ex rel. Attorney Gen. v. Del. & Hudson Co.*, 213 U.S. 366, 407-408 (1909); *Parsons v. Bedford*, 3 Pet. 433, 448-49 (1830)(Story J.); *Murray v. The Charming Betsy*, 6 U.S. 64, 118 (1804)); *see also Hooper v. California*, 155 U.S. 648, 657 (1985); *Grenada County Supervisors v. Brogden*, 112 U.S. 261, 269 (1884).

III. THE DECISION BELOW VIOLATES *CARDOZA-FONSECA* AND THIS COURT'S STATUTORY CONSTRUCTION PRECEDENT BY ACCORDING DEFERENCE TO FDA'S INTERPRETATION OF 21 U.S.C. § 343(r)(1)(B) DESPITE PLAIN STATUTORY LANGUAGE TO THE CONTRARY, CONGRESSIONAL PRE-ENACTMENT KNOWLEDGE OF, AND FAILURE TO ADOPT, FDA'S FAVORED MEANING, AND LEGISLATIVE INTENT THAT CONTRADICTS FDA'S INTERPRETATION

The panel determined under *Chevron* step two that FDA was reasonable in interpreting 21 U.S.C. § 343(r)(1)(B) (describing health claims for dietary supplements as statements that "characterize[] the relationship of any nutrient . . . to a disease or health-related condition") when FDA chose to exclude from allowable health claims all claims of the effect of nutrients on existing disease. Pet. App. at 7a-8a. The panel decision thus renders such claims illegal for dietary supplements and only available if the unpatentable nutrients in question were first approved as new drugs under 21 U.S.C. § 355(a) (2000 & Supp. I 2002).

The panel found FDA's definitional constriction reasonable despite recognizing that the literal wording of 21 U.S.C. § 343(r)(1)(B) defines health claims more broadly, as any nutrient-disease relationship claim. Pet. App. at 3a.[9] The panel stated that none of the government's arguments in favor of the definitional constriction was "a knock-down argument, and we doubt that any of them would be sufficient to over-

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[9] *Compare United States v. Labonte*, 520 U.S. 751, 757 (1997) ("We do not start from the premise that [the statutory language] is imprecise. Instead, we assume that in drafting legislation Congress said what it meant"); *Pub. Employees Ret. Sys. v. Betts*, 492 U.S. 158, 171 (1989) (the "plain language" rule of statutory construction); *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 810 (1989).

come a strong textual or structural inference in favor of a different interpretation." *Id.* at 7a. The panel nevertheless failed to explain how it could find FDA's interpretation of the statute reasonable (1) in light of the absence of any clear statement in the legislative history contradicting the statute's plain meaning and (2) in the presence of legislative history that greatly favors the plain meaning. The panel failed to follow this Court's decision in *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987). In so doing, violated this Court's statutory construction precedent and it contradicted the decisions of the other circuits. *Cf. Mass. Ass'n of HMOs v. Ruthardt*, 194 F.3d 176, 185 (1st Cir. 1999) ("Congress can sometimes speak as clearly by opting not to enact proffered language as by enacting it"); *Id.* (". . . when Congress speaks, courts charged with the delicate work of statutory construction should listen"); *Benjamin v. Fraser*, 343 F.3d 35, 46-47 (2d Cir. 2003) ("Well-settled principles of statutory construction dictate that 'where Congress includes limiting language in an earlier version of a bill but delete it prior to enactment, it may be presumed that the limitation was not intended'") (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)). The panel omitted any evaluation of the reasoning in *Cardoza-Fonseca*, that "few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." 480 U.S. at 442-443, citing *Nachman Corp. v. Pension Benefit Guar. Corp.*, 446 U.S. 359, 392-393 (1980) (citations omitted).

Congress had before it FDA's preferred "prevention only" health claims definition at the time it debated passage of 21 U.S.C. § 343(r)(1)(B), but Congress did not codify FDA's preferred definition. H.R. REP. NO. 101-538, Pub. L. No. 101-535 (Feb. 13, 1990). In 1990, FDA reproposed a 1987 rule concerning the use of what FDA then called "health messages" (*i.e.*, what FDA now calls "health claims") in food

labeling. 55 Fed. Reg. 5176 (Feb. 13, 1990). In that reproposal, FDA defined a health message as "the value that ingestion (or reduced ingestion) of a dietary component may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease." *Id.* at 5192. In that reproposal, FDA specifically excluded "treatment" claims. *Id.* at 5178. Congress was aware of the reproposal during the NLEA debates. Indeed, the reproposal is cited in the House Report on the bill. H.R. REP. NO. 101-538 at 9, 22. FDA admits that in drafting the NLEA Congress was in agreement with FDA on two propositions in the reproposed rule. Motion to Dismiss at 23. However, Congress did not adopt FDA's definition of "health messages," *i.e.*, of health claims. Aware of FDA's "prevention only" definition, Congress drafted the far broader language appearing in the statute: "characterize[] the relationship of any nutrient . . . to a disease or health-related condition." 21 U.S.C. § 343(r)(1)(B). There is no clear legislative intent supporting FDA's "prevention only" interpretation of § 343(r)(1)(B). While the panel cites instances in which members of Congress refer to claims of disease risk reduction, not a single member states that those are the only kinds of nutrient-disease relationship claims allowable, and none states that claims of a nutrient's effect on existing disease are disallowed. H.R. REP. NO. 101-538 at 22. Under *Cardoza-Fonseca*, 480 U.S. 421, the reproposed rule is compelling evidence that Congress intended the literal meaning of the statutory language it chose. *See id.* at 442-43.

The panel also cited selectively from the NLEA House Report, H.R. REP. NO. 101-538, not recognizing any materiality associated with House Report statements that contradict the premise that Congress meant § 343(r)(1)(B) to be limited to "prevention" claims. Two passages, describing "health claims" pre-NLEA, reveal that Congress contemplated

treatment as well as prevention when it used the term "health claims:"

> . . .[D]uring the mid-1980's, companies began making health claims on foods, even though the FDA had not approved the claims through the drug approval process. Those statements claimed that the food was valuable in the prevention or treatment of various diseases. Subsequently, the FDA published proposed regulations that sanctioned this practice by permitting manufacturers to make disease-specific claims that had not met the FFDC Act's requirements applicable to drugs. 52 Fed. Reg. 28,843 (August 4, 1987).

H.R. REP. NO. 101-538 at 9.

> Moreover, there is a serious question as to whether the Agency has the legal authority to implement the program that it has proposed, which would permit health claims regarding the usefulness of a food in treating a disease, without also requiring that the claim meet the premarket approval requirements applicable to drugs.

Id. In the NLEA House Report cited by the panel, there is no statement limiting "health claims" to disease prevention. Had the Circuit followed *Cardoza-Fonseca*, 480 U.S. at 442-443, the statute's plain meaning would govern. There is no clear legislative intent supporting FDA's interpretation, and there is direct evidence that Congress rejected that interpretation.

This Court should exercise its discretionary review to reject the Circuit's decision and ensure adherence to this Court's statutory construction canons.

IV. UNLESS REVERSED, THE CIRCUIT DECISION WILL BLOCK IN PERPETUITY TRUTHFUL INFORMATION ABOUT THE EFFECTS OF FOODS AND DIETARY SUPPLEMENTS ON DISEASE FROM ENTERING CONSUMER MARKETS

Information about the extent to which modifications in one's diet, including ingestion of a food or a dietary ingredient, may reduce the length, severity, or symptoms of a disease has great value for those so afflicted. Knowing how food interacts with disease can guide consumers in making wise dietary choices that can help them cope with chronic disease or hasten their return to good health. The FDA decision upheld by the panel casts a pall of censorship on this kind of information at the point of sale, prohibiting from markets facts needed for the exercise of informed choice. The decision and its suppressive effects, reaching all unpatentable foods and dietary supplements, offend core First Amendment principles by reversing the premise that "if the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so"[10] and by substituting for that premise the notion repeatedly rejected by this Court that government is better left to decide the relative worth of truthful commercial information than the individual.[11]

The cost of new drug approval is uneconomic for companies that sell unpatentable foods and unpatentable dietary supplements, at an estimated $200 million per drug approval

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[10] *W. States Med. Ctr.*, 535 U.S. at 371.

[11] *Edenfield*, 507 U.S. at 767 ("[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented"); *see also, W. States Med. Ctr.*, 535 U.S. at 367, 374-75; *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976) ("[T]he free flow of commercial information is indispensable").

(at least $58 million in the case of saw palmetto extract). Br. for Appellants at 6, n.14. Congress contemplates patentability in the FDCA's drug provisions. 21 U.S.C. § 355(b)(1), (c)(2) and (c)(3)(D) (2000 & Supp. I 2002). Even were foods and nutrients patentable, the FDA has already explained that foods are unlikely to satisfy new drug approval requirements. *Id.* at 6-7. Moreover, to communicate nutrient-disease information about the foods and the supplements they sell, few food and dietary supplement companies would accept the condition precedent that their products be regulated and sold as drugs. *Id.* at 6.

In this case, information concerning the effect of saw palmetto extract is being kept from the market despite the fact that the extract is commonly sold nationwide without objection from FDA. The information is being kept from the market despite the fact that it would aid consumers in identifying a low cost means to alleviate symptoms of mild benign enlarged prostate, a condition afflicting 40 to 50% of men over the age of 50. Br. for Appellants at 2, n.2. Countless males who presently suffer from the symptoms of mild, benign enlarged prostate could receive relief were they aware of the truthful information Petitioners wish to convey and the FDA now censors.[12]

To return the law to its constitutional moorings and guard against erosion of this Court's First Amendment, avoidance doctrine, and statutory construction precedent, the Court should grant the writ and reverse the panel decision.

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[12] *Cf., W. States Med. Ctr.*, 535 U.S. at 376 ("If the Government's failure to justify its decision to regulate speech were not enough to convince us that the FDAMA advertising prohibitions were unconstitutional, the amount of beneficial speech prohibited by the FDAMA would be . . . . It would prevent pharmacists . . . who serve clienteles with special medical needs from telling the doctors treating those clients about the alternative drugs available through compounding").

The panel decision conflicts with this Court's and other circuits' interpretation of the first prong of *Central Hudson*. The panel decision alters the 200-year old standard for invocation of the avoidance doctrine contrary to this Court's precedent and that of the other circuits. The panel decision violates this Court's canons of statutory construction and the conforming precedent of the other circuits. Accordingly, this Court should grant the writ, reverse the panel decision, and resolve the issues raised to ensure the protection of truthful commercial speech. Consumers should be entitled to receive truthful information producers wish to communicate concerning how foods and the constituents within them affect disease. The FDA's censorship, condoned by the Court below, will continue unabated, suppressing great quantities of truthful health information, unless this Court grants the writ and reverses the panel's decision.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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